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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,082	01/09/2004	Brian Dalby	38-03	8189

23713 7590 05/12/2006

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,082	DALBY ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-117 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-117 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-30, drawn to a method of delivering a polypeptide to a cell comprising contacting said cell with said polypeptide, a nucleic acid, a fluorescent molecule, and a cellular delivery molecule, and treating the cell with a treatment that causes dissociation of said polypeptide from one or more of said nucleic acid, said fluorescent molecule, and said cellular delivery molecule, classified in class 514, subclass 2.
2. Claims 31-38, drawn to kit comprising a fluorescent molecule and at least one cellular delivery molecule, classified in class 514, subclass 1.
3. Claims 39 and 40, drawn to kit comprising at least one transfection agent and at least one RNAi molecule, classified in class 536, subclass 23.1.
4. Claims 41-60, drawn to a complex comprising a cellular delivery polypeptide and an agent, wherein the cellular delivery polypeptide comprises a fluorescent moiety, classified in class 530, subclass 350.
5. Claims 61-90, drawn to a method of delivering a nucleic acid to a cell comprising contacting said cell with said nucleic acid, a fluorescent molecule, and a cellular delivery molecule, and treating the cell with a treatment that causes dissociation of said nucleic acid from one or both of

said fluorescent molecule, and said cellular delivery molecule, classified in class 435, subclass 455.

6. Claims 91-104 drawn to a complex comprising one or more nucleic acids, one or more fluorophores, and one or more cellular delivery polypeptides, wherein each cellular delivery polypeptide has 10-100% basic amino acids, comprises a sequence of contiguous basic amino acids of between 2 and 50 amino acids in length, and is not derived from a herpes simplex virus protein, classified in class 536, subclass 23.1.

7. Claims 105-107, drawn to a method of treating an individual suffering from a disease or disorder by contacting said individual with a complex comprising one or more nucleic acids, one or more fluorophores, and one or more cellular delivery polypeptides, wherein each cellular delivery polypeptide has 10-100% basic amino acids, comprises a sequence of contiguous basic amino acids of between 2 and 50 amino acids in length, and is not derived from a herpes simplex virus protein, classified in class 514, subclass 44.

8. Claims 108-117, drawn to a method of detecting a cellular response to a test compound or identifying a test compound having a preselected activity or effect, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Invention 1 is related to inventions 2-4 and 6 as related as a process of use to products. The inventions can be shown to be distinct if either or both of the following

can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the components of the kits of inventions 2 and 3 could be combined for use in the method of invention 1, however, these components need not be combined, and could be used separately in different methods not requiring the particulars of invention 1. For example, the fluorescent molecule and at least one cellular delivery molecule of invention 2 could be used simply for the purpose of cell labeling without delivery of the polypeptide required by invention 1. The at least one transfection agent and at least one RNAi molecule of invention 3 could be used by themselves to transfect a cell, without need of the polypeptide of invention 1 or the cellular delivery molecule of invention 2. The complex of invention 4, comprising a fluorescent cellular delivery polypeptide and an agent could be used by itself to deliver the agent to a cell, without need of the polypeptide or nucleic acid required by invention 1, or the RNAi molecule of invention 3. Furthermore, the components of the kits of inventions 2 and 3 need not form a complex as required by invention 4. The complex of invention 6 could be used by itself to deliver the nucleic acid to a cell, without need of the polypeptide required by invention 1. Also, the components of the kits of inventions 2 and 3 need not form a complex as required by invention 6. Finally the complex of invention 6 does not require a fluorescent delivery polypeptide, and the agent of invention 4 need not be a nucleic acid.

Inventions 1 and 5 are related but distinct methods. Invention 1 requires the delivery of a polypeptide to a cell, whereas invention 5 requires delivery of a nucleic acid to a cell. While the method of invention 1 will result in delivery to a cell of a nucleic acid, the intended result is the delivery of a particular polypeptide. Invention 5 does not require the delivery to a cell of the polypeptide of invention1, instead it requires delivery of a polynucleotide.

Inventions 1 and 7 are related but distinct methods. Both methods require use of a nucleic acid, a cellular delivery molecule and a fluorescent entity. However, invention 1 is a method of delivering a polypeptide to a cell, whereas invention 7 is a method of treating an individual suffering from a disease. Invention 7 does not require the polypeptide of invention 1, and invention 1 does not require contacting an individual with any substance or treatment of any disease. Invention 7 does not require delivery to a cell. Thus the methods do not require the same reagents, use the same steps, or require the same effects.

Inventions 1 and 8 are related but distinct methods. Both methods require use of a nucleic acid, a cellular delivery molecule and a fluorescent entity. However, invention 1 is a method of delivering a polypeptide to a cell, whereas invention 8 is a method of determining a cellular response to a test compound. Invention 8 does not require the polypeptide of invention 1, and invention 1 does not require determining a cellular response to a test compound. Thus the methods do not require the same reagents, use the same steps, or require the same effects.

Inventions 2-4 and 6 are related to invention 7 as products to a process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the components of the kits of inventions 2 and 3 could be combined for use in the method of invention 7, however, these components need not be combined, and could be used separately in different methods not requiring the particulars of invention 7. For example, the fluorescent molecule and at least one cellular delivery molecule of invention 2 could be used simply for the purpose of cell labeling in vitro without delivery of the nucleic acid, or the treatment of the individual, required by invention 7. The at least one transfection agent and at least one RNAi molecule of invention 3 could be used by themselves to transfect a cell in vitro, without need of the fluorescent molecule or the cellular delivery molecule of invention 7. The complex of invention 4, comprising a fluorescent cellular delivery polypeptide and an agent could be used by itself to deliver the agent to a cell in vitro, as well.

Inventions 2-4 and 6 are related to invention 8 as products to a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the components of the kits of inventions 2 and 3 could be combined for use in the method of invention 8, however, these components need not be combined, and could be used

separately in different methods not requiring the particulars of invention 8. For example, the fluorescent molecule and at least one cellular delivery molecule of invention 2 could be used simply for the purpose of cell labeling, without determination of any cellular response as required by invention 8. The at least one transfection agent and at least one RNAi molecule of invention 3 could be used by themselves to transfect a cell, without need of the fluorescent molecule or the cellular delivery molecule of invention 8. The complex of invention 4, comprising a fluorescent cellular delivery polypeptide and an agent could be used by itself to deliver the agent to a cell, without need of the cellular delivery molecule of invention 8.

Inventions 5 and 7 are related but distinct methods. Both methods require use of a nucleic acid, a cellular delivery molecule and a fluorescent entity. However, invention 5 is a method of delivering a nucleic acid to a cell, whereas invention 7 is a method of treating an individual suffering from a disease. Invention 1 does not require contacting an individual with any substance or treatment of any disease. Invention 7 does not require delivery to a cell. Thus the methods do not use the same steps, or require the same effects.

Inventions 5 and 8 are related but distinct methods. Both methods require use of a nucleic acid, a cellular delivery molecule and a fluorescent entity. However, invention 5 is a method of delivering a nucleic acid to a cell, whereas invention 8 is a method of determining a cellular response to any test compound. Invention 1 does not require determining a cellular response to a test compound. Thus the methods do not require use the same steps, or require the same effects.

Inventions 7 and 8 are related but distinct methods. Both methods require use of a nucleic acid, a cellular delivery molecule and a fluorescent entity. However, invention 7 is a method of treating an individual suffering from a disease, whereas invention 8 is a method of determining a cellular response to a test compound. Thus the inventions are directed to entirely different objectives and result in entirely different outcomes.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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